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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,583	02/05/2001	Karl-Hermann Schlingensiepen	P66141US0	7033

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,583	SCHLINGENSIEPEN ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7, 8, 11-13 drawn to a medicament comprising a nucleic acid inhibitor and a stimulator of an immune response in a method to treat neoplasms, classifiable in class 514, subclasses 1 and 44.

II. Claims 1, 2, 6-8, 11-13 drawn to a medicament comprising an antibody inhibitor and a stimulator of an immune response in a method to treat neoplasms, classifiable in class 514, subclasses 1 and 2.

III. Claims 1-5, 7, 8, 11-13 drawn to a medicament comprising a nucleic acid inhibitor and a stimulator of an immune response in a method to treat infectious diseases, classifiable in class 514, subclasses 1 and 44.

IV. Claims 1-5, 7, 8, 11-13 drawn to a medicament comprising a antibody inhibitor and a stimulator of an immune response in a method to treat infectious diseases, classifiable in class 514, subclasses 1 and 2.

V. Claim 9, drawn to a medicament comprising multiple inhibitors and a stimulator, classified in class 530 and 536, subclasses 387.1 and 24.5, respectively.

VI. Claims 10, 11, drawn to nucleic acid compositions, classified in class 536, subclass 24.5.

Please elect a single substance from claim 1.

Please elect a single stimulator from claim 8.

Please elect a single nucleotide sequence from claim 10, for the reasons set forth below:

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the nucleotide sequences listed in claim 10 are subject to restriction. As per M.P.E.P. 2434, "the Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide or amino acid sequences to be claimed in a single application." Under this policy, in most cases, up to 1 (one) independent and distinct nucleotide OR amino acid sequence will be examined in a single application without restriction. Those sequences which are patentably indistinct from the sequence selected by the applicant will also be examined.

Claim 10 specifically claims nucleotide sequences encoding antisense targeting various target nucleic acids, and these individual SEQ ID Nos. are listed in claim 10. Each of these antisense sequences is considered to be structurally independent, because each of these sequences has a unique nucleotide sequence, and each targets a specific region of a particular gene or a specific target gene. Furthermore, a search of all the sequences claimed presents an undue burden on the Patent and Trademark Office to search and examine all of the recited sequences. In view of the foregoing, applicants are required to elect up to 1 claimed nucleotide sequence from the claim.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II and III and IV and V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise compositions or compounds that are chemically, biologically, structurally and functionally distinct from each other and thus one does not render the other obvious. The nucleic acids are different and distinct from each other (Groups I, III, V, VI), and are different and distinct from the antibodies (Groups II, IV, V). The nucleic acids are not required to produce the antibodies or the other nucleic acids. Therefore, the inventions of the various groups are capable of supporting separate patents.

Inventions I and II and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise biologically and functionally different and distinct Groups and thus one does not render the other obvious. The methods of Groups I and II and III and IV comprise steps which are not required for or present in the methods of the other groups: administration of compositions comprising nucleic acid inhibitors which target different genes for treatment of neoplasia or infectious diseases (Groups I and III, respectively), administration of compositions comprising antibodies for treatment of neoplasia or infectious diseases (Groups II and IV, respectively). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore,

the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is **703-872-9306**. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (571) 272-0760. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JZ
January 30, 2004

SEAN McGARRY
PRIMARY EXAMINER
1685